DEPARTMENT OF HEALTH AND HUMAN SERVICES

FOOD AND DRUG ADMINISTRATION

CENTER FOR DEVICES AND RADIOLOGICAL HEALTH

GENERAL AND PLASTIC SURGERY DEVICES PANEL

OF THE MEDICAL DEVICES ADVISORY COMMITTEE

OPEN SESSION

60th Meeting

Tuesday, July 9, 2002

8:00 a.m.

Gaithersburg Holiday Inn
Two Montgomery Village Avenue
Gaithersburg, Maryland

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Nancy A. Dubler, LLB
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LeeLee Doyle, Ph.D.

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Debera M. Brown

C O N T E N T S

C O N T E N T S (Continued)

P R O C E E D I N G S

Call to Order, Conflict of Interest and Opening Remarks

DR. KRAUSE: If everybody would take a seat, I would like to start the meeting. I would like to say good morning to everybody. Thank you for coming. We will try to start the public testimony as close to 8:30 as possible for those people who looked at the schedule to see what time the public comment period would be. I don't want to rush things but I want to make sure everybody who wants to speak who is on our list gets a chance.

We are ready to continue the 60th meeting of the General and Plastic Surgery Devices Panel. My name is David Krause. I am the executive secretary of the panel. I am also a biologist and a reviewer in the Plastic and Reconstructive Surgery Device Branch, in the Division of General, Restorative and Neurological Devices.

I would like to remind everyone to please sign in on the attendance sheets which are just outside the door. You can also pick up an agenda, a panel meeting roster and information about today's meeting at the tables just outside the

door. The information provided includes how to find out about future meeting dates through the advisory panel phone line, and also how to obtain meeting minutes or transcripts.

Before turning the meeting over to Dr. Whalen, I would like to read today's conflict of interest statement. The following announcement addresses conflict of interest issues associated with this meeting, and is made a part of the record to preclude even the appearance of an impropriety.

To determine if any conflict existed, the agency reviewed the submitted agenda and all financial interests reported by the committee participants. The conflict of interest statutes prohibit special government employees from participating in matters that could affect their or their employers' financial interests. However, the agency has determined that participation of certain members and consultants, the need for whose services outweighs the potential conflict of interest involved, is in the best interest of the government.

Therefore, a waiver has been granted for Dr. DeMets for his interests in a firm that could potentially be affected by the panel's

recommendations. The waiver allowing him to participate fully in today's deliberations involves a contract to his employer and his consulting services with a competing technology firm. His employer receives funding between $100,000.00 and $300,000.00 per year on the contract that is unrelated to today's agenda. For his unrelated consulting service, he receives less than $10,000.00 a year. Copies of this waiver may be obtained from the agency's Freedom of Information Office, Room 12A-15 of the Parklawn Building.

We would like to note for the record that the agency took into consideration certain matters regarding Dr. DeMets and Dr. Miller. Dr. DeMets reported an interest with a firm at issue, but in a matter that is not related to today's agenda. Dr. Miller reported that his institution has a current related involvement with a firm at issue. The agency has determined that these individuals may participate fully in the panel's deliberations.

In the event that the discussions involve any other products or firms not already on the agenda for which an FDA participant has a financial interest, the participant should excuse him or herself from such involvement and the exclusion

will be noted for the record.

With respect to all other participants, we ask in the interest of fairness that all persons making statements or presentations disclose any current or previous financial involvement with any firm whose products they may wish to comment upon.

I would now like to turn the meeting over to the Chairman, Dr. Whalen.

DR. WHALEN: Thank you, Dr. Krause. Good morning. My name is Dr. Thomas Whalen. I am professor of surgery and pediatrics at Robert Wood Johnson Medical School in New Brunswick, New Jersey.

Today our panel will be making a review and update of previously approved premarket applications which were approved in May of 2000. Although we are in our second day of business as a panel, I believe we have a considerably different audience than we did yesterday, so we will ask our panel members to reintroduce themselves to the audience, acknowledging that these are panel members who are giving of their time to help the FDA in these matters, and I would also ask the FDA staff at the table to introduce themselves as well.

Each person is asked to introduce himself

by name and state specialty and position title, starting on my left with Ms. Brown, please.

MS. BROWN: I am Debera Brown. I am the vice president of regulatory affairs for Broncus Technologies. I am also the industry representative for this panel.

DR. DOYLE: I am LeeLee Doyle. I am professor of obstetrics and gynecology and associate dean for continuing medical education and faculty development with the University of Arkansas for Medical Sciences, College of Medicine, and I am the consumer representative on the panel.

DR. MCCAULEY: Robert McCauley, professor of surgery and pediatrics, University of Texas Medical Branch and chief of plastic surgery services for the Shriner's Burns Hospital in Galveston, Texas.

DR. DUBLER: I am Nancy Dubler. I am an attorney and the director of the Division of Bioethics at Montefiore Medical Center, and a professor of epidemiology and social medicine at the Albert Einstein College of Medicine.

DR. CHOTI: I am Michael Choti, associate professor of surgery and oncology, in the Division of Surgical Oncology at Johns Hopkins Hospital in

Baltimore, Maryland.

DR. NEWBURGER: I am Amy Newburger. I am a dermatologist in private practice, in New York. I am an attending physician at White Plains Hospital Medical Center. I teach at St. Luke's Roosevelt Medical consortium in New York.

DR. DEMETS: I am David DeMets. I am professor and chair of the Department of Biostatistics and Medical Informatics at University of Wisconsin, in Madison. I am a statistician by degree and I have a long history and interest in clinical trials.

DR. CHANG: I am Phyllis Chang, associate professor in the Division of Plastic Surgery, Department of Surgery, and Division of Hand and Microsurgery, Department of Orthopedic Surgery at the University of Iowa College of Medicine, in Iowa City.

DR. MILLER: I am Michael Miller, associate professor of plastic surgery at University of Texas, MD Anderson Cancer Center.

DR. WITTEN: Celia Witten, division director of the Division of General, Restorative and Neurological Devices at the FDA.

DR. WHALEN: Thank you all. I would like

to note for the record that the voting members present constitute a quorum, as required by 21 CFR Part 14. At this point, I would like to turn the meeting back to you, Dr. Krause, for a moment.

DR. KRAUSE: Thank you, Dr. Whalen. Just for the record, I would like to say that Dr. Miller, Dr. Chang, Dr. DeMets, Dr. Choti and Dr. McCauley are voting members on the panel. Ms. Dubler and Dr. Newburger are temporary voting members on the panel for today's meeting.

I would like to make some brief remarks before we get into the main body of today's panel discussion. Today is the last meeting for a number of our distinguished panelists. It is the last meeting for Dr. Whalen, our Chairman, and for Dr. DeMets and Dr. Chang who are voting members. I would also like to acknowledge that Dr. Joe Boykin's term has also ended. He was unable to attend today. These panelists have served this panel with distinction for the past four years and I would like to thank them for their service. I would like to ask Dr. Witten to please make a few remarks at this time.

DR. WITTEN: Thank you. We are very sorry to be saying goodbye to our panel members who are

with us for the last time today. We rely on our panel members for their expertise in helping us make our regulatory decisions. Panel members give their time to us to serve FDA and, in doing so, serve public health in helping us make good regulatory decisions. I am particularly sorry about saying goodbye to the three people at the table today.

I have a letter, singed by Linda Sudan, the senior associate commissioner for communications and constituent relations, which I will read, the same letter to all the panel letters who are leaving:

Dear Dr. Whalen, I would like to express my deepest appreciation for your efforts and guidance during your term as a member and chair of the General and Plastic Surgery Devices Panel of the Medical Devices Advisory Committee.

The success of this committee's work reinforces our conviction that responsible regulation of consumer products depends greatly on the experience, knowledge and varied background and viewpoints that are represent on this committee. In recognition of your distinguished service to the Food and Drug Administration, I am pleased to

present you with this plaque, which is not enclosed but will be coming separately.

I have the same letter for Dr. Whalen, Dr. Chang and Dr. DeMets and also for Dr. Miller. We will be hoping to see you again as consultants on some projects in the future.

DR. KRAUSE: Thank you, Dr. Witten. I would like to now turn the meeting back over to Dr. Whalen.

Open Public Comment

DR. WHALEN: Thank you. We will now proceed with the open public comment session of the meeting. I would like to remind everyone who wishes to address the panel to please speak clearly into the microphone as the transcriptionist is dependent on this means to provide an accurate record of this meeting. In addition, if anyone has printed copies of their remarks, if they could hand them over to the table on my left, to the transcriptionist, that would be deeply appreciated.

At this time, Dr. Krause has some additional instructions for those who will be testifying before the panel. Dr. Krause?

DR. KRAUSE: Thank you, Dr. Whalen. I have some instructions for those of you who will be

testifying to the panel this morning. We are requesting that all persons making statements during the open public hearing of the meeting disclose whether they have financial interests in any medical device company, or if their trip to this meeting has been paid for by someone else.

Before making your presentation to the panel, in addition to stating your name and affiliation, please address the following questions. I will read the questions into the record once so that we don't have to do it when every speaker speaks. The questions are as follows:

Question one, has your travel and/or accommodations been paid for or will they be reimbursed by someone else? If so, please state who.

Question number two, please indicate whether you have financial ties, including grants or other compensation, with industry or health professional societies.

Question number three, please indicate whether you are a party to or a witness in a pending lawsuit related to breast implants.

Question four, do you derive a portion of

your income from surgical procedures using saline-filled implants or from treating patients with complaints that they believe are related to saline-filled implants?

I would like to have the attention of all the individuals who have registered to speak to the panel today. You have all been put in the proper order by Anne Marie. Anne Marie will direct you to the podium or, hopefully, she has given you some instructions. At this point, we are going to limit everyone to five minutes. At the end of each presentation, please stay at the podium in order to give the panelists a chance to ask you any questions, if they have any questions.

I would now like to return the meeting to Dr. Whalen.

DR. WHALEN: Thank you, Dr. Krause. We are required by law to allot one hour for public testimony. Today, because of the nature of the topic that we are dealing with, we have decided to allot two full hours. I realize, by the nature of the topic that we are dealing with and from the experience that we had as a committee two years ago in dealing with the PMAs on this, that there are some very deeply held convictions and sentiments

about this topic. So, I will apologize in advance if I cut you off at the five-minute limit, acknowledging the depth of your conviction about what you are speaking about. I am not trying to be rude, but simply trying to accommodate everyone who wishes to speak on this topic today because of the number of people who have come forward wishing to speak.

Also, I have been given an order of speakers that I will follow. I understand that there may be some mild confusion about who was to follow whom, but please bear with me on this. At the end of going through everyone that I have had identified to me being called by name, I will have an open announcement for anyone else wishing to speak as long as we still have more of that two-hour time period for people to address the panel.

Therefore, the first person that I have identified is Ms. Arlene Nicole Cummings, from Implantinfo.com. Is Ms. Cummings available?

[No response]

Very well. The second one is Ms. Tammy Griffiths, representing herself.

MS. GRIFFITHS: Good morning. I would

like to thank the committee for allowing me to speak today. I come here today of my own accord--

DR. KRAUSE: Could you excuse me a minute, you weren't here when I read the questions. There are four questions you need to address before you start. Let me read them again: Have your travel or accommodations been paid for, or will they be reimbursed by someone else? If so, please state who.

Second question, please indicate whether you have financial ties, including grants or other compensation, with industry or health professional societies.

Number three, please indicate whether you are a party to or witness in a pending lawsuit related to breast implants.

Question four, do you derive a portion of your income from surgical products using saline-filled implants or from treating patients with complaints that they believe are related to saline-filled implants?

If you could just answer those questions before you start. That goes for everybody. Thank you.

MS. GRIFFITHS: Sorry about that. No to

all of the above questions.

I come here today of my own accord in support of the continued use of saline breast implants. My name is Tammy, and I am 38 years old and the mother of four children, ranging in ages 5 to 13 years old. I have been married for 15 years, and my husband and I own and operate a heating and air conditioning company in Texas.

I received a breast augmentation in January of 1999. Breast feeding four children had taken a toll on me physically, and the availability of breast implants gave me an option. To me, this was, indeed, a gift both physically and emotionally that I have never regretted.

Prior to my children, I was very content with my breast size which was proportionate to my small frame. However, I was through with my childbearing years, and at the age of 34, I was very unhappy with the resulting shape of my breasts. Nursing four babies had taken quite a toll on my physique. With each child I would swell from my normal 34B cup to a 36D cup. Once each child weaned, I would return to the 34B cup but each time with less lift texture than I had before.

After my fourth child was through nursing,

my breasts were once again a 34B only they appeared depleted, flat and shapeless, and they no longer felt firm. It was almost as if I had nothing at all. I began working at the gym on a regular basis especially concentrating on my pectoral muscles, trying to build them back up, but to no avail. Then I tried a pair of silicone bran inserts to wear underneath my clothing just so that it would appear that I had breasts. However, when I looked in the mirror and it was just me, all by myself, I remained unsatisfied with my look and began to explore other options. The mirror did not lie.

My husband Randy and I began to consider breast augmentation as an option. He was, and still is, 100 percent supportive. We both started reading everything we could find on the subject. We read medical reports; we read opinions both for and against the procedure. After research, we considered all the pros, cons, risks, rewards, side effects, both physical and emotional. As with any elective surgery, we desired to make an informed decision and so we did.

After much discussion, Randy told me the final decision was mine to make. He was happy either way and was just satisfied that the medical

procedure was a safe option. He continued to support me totally. I made the decision to have surgery and have never regretted it. I located a doctor in my area and again asked many questions.

Once I was satisfied with the doctor, we set a date and the surgery was completed without incident. I now have Mentor saline implants. I am slightly larger than I was prior to having children but, most importantly, I feel better about myself now than I did prior to surgery.

I can tell you that this is one of the best decisions or gifts, if you will, that I could have given myself. I am now three and a half years postop and very happy with my results. I have found myself feeling even more confident as a woman when I am in a business suit, a swimsuit or just attending a PTA meeting dressed in casual, conservative attire. I truly believe I am a wife and a mother who is not only well adjusted in her life, but a wife and mother who is also self-confident in her physical appearance wherever I happen to be.

In closing, I would like to say that I feel it is most important that breast augmentation with saline implants continue to be an option for

all women, whether they are cancer survivors, whether they need some other type of reconstruction, or if they just want something different. Given good information and good medical care, saline implants are not only a viable solution for a variety of circumstances but they are safe as well, in my opinion. Thank you.

DR. WHALEN: Thank you, Ms. Griffiths. Are there members of the panel who have any questions?

[No response]

Thank you very much. Before the next speaker is called for, just to remind people--I certainly wouldn't remember all those four questions, so if anyone gets up to the podium and needs a prompt for the four questions, just indicate that to me and I will be happy to give you the topics of each of the areas that you need to start off with. Also, to answer those questions obviously isn't part of your five minutes. The next identified speaker is Ms. Denise King.

MS. KING: In answer to all of your questions, the answer is no. Thank you for the privilege of allowing me to speak today. My name is Denise. I am 43 years old and have been married

for 22 years. My husband and I have 6 children, ranging in ages from 17 to 7 years.

After nursing all of my children, some for as long as 18 months, and losing the large amount of weight that I had gained due to six pregnancies, my breasts were left deflated, hollow looking. They looked as though they belonged to a woman twice my age. It was both physically and emotionally uncomfortable to have the upper part of my body in this condition because I have worked so hard to maintain my weight.

After a lot of thought, research and extensive consultation with a board-certified plastic surgeon, after several discussions with other women that had had breast augmentation, asking both what they did and did not like about implants, on August 7 of 2001, and with the full support of my husband, I underwent a five-hour surgery to reconstruct my breast with an anchor style lift and under the muscle placement of saline implants. I received nothing less than excellent care from my physician both before, during and after my surgery.

I have followed my doctor's instructions to the letter. I see him every 12 weeks so that

any possible problems may be detected quickly. In the past 11 months I have been asked several times if I have ever regretted having the surgery. My answer is that there are no regrets because this was something that I did for my self-esteem.

In closing, I would like to say that I believe that every woman should have the right to decide for herself whether she wants to pursue changing her shape through breast augmentation. It is also my belief that women need to have available to them as much information about implants and the surgical procedure as possible, enabling them to make a well-informed decision. Thank you again for your time.

DR. WHALEN: Thank you, Ms. King. Any questions? [No response]

Thank you very much. Next is Ms. Cheryl Valput.

MS. VALPUT: No to all the four questions. Good morning. I would also like to thank the committee today for allowing me to speak. My name is Cheryl Valput. I am 45 years of age, reside in Ohio with my husband of 22 years and two daughters, ages 19 and 16. I am a full-time mom and business owner of a real estate company with my husband.

I had breast augmentation done three years ago, in Cleveland, Ohio by Dr. Richard Dowden. This was one of the best decisions that I have made in my life. I am not a model, a dancer or a movie star but I felt that this was something I needed to do for me. I came to this decision for myself because I had to balance a difference in my breast size. I felt uneven every time I looked in the mirror. I was tired of stuffing one side of a bra, making sure I looked normal in a bathing suit. My self-confidence was low and I knew that I had a choice in the matter to change my appearance.

I did research for over six months and read everything I could about breast implants, the good and the bad. I finally decided that I was either going to proceed with the surgery or put it out of my mind for good. I deserved to look my best and called Dr. Dowden. I have saline anatomical McGhan's shaped implants under the muscle. I went from an A cup to a C cup and finally they were both the same size. Looking in the mirror wasn't so bad after all.

After surgery I could wear the clothing I desired and my self-confidence has been at its best. When you feel so good on the inside, it is

hard not to feel beautiful on the outside. This is a very personal decision I made, along with my husband's support every step of the way.

For me, to stand and speak in front of the committee today took some thought. I don't talk about this with everyone. My own parents and sisters haven't been told about my surgery, but I feel very strongly about having the choice of getting breast implants. It is not because I am trying to hide anything, but it is a decision that had to be made for myself. Taking that choice away from women could not, and would not be right. We color our hair; fix our teeth; choose the car we want to drive; and change our eye color. We have the right to change our breast size and shape if we choose to.

I haven't had any complications and I am fully aware of the risk of implants. The decision of this must rest on the balance between how strongly you want the benefits versus how worried you are about the risk. Life is a risk, but I would rather go through life looking and feeling this way than without that. Thank you.

DR. WHALEN: Thank you. Again, no questions?

[No response]

Thank you very much. Next is Ms. Melanie Palmer.

MS. PALMER: The answer to all your questions is no. Good morning. My name is Melanie Palmer. I am 46 years old, from Ohio. I have a husband, Tom, and two children ages 15 and 20. Thank you for allowing me to speak to day on behalf of women who are seeking the possibility of breast augmentation.

Breast augmentation is not only a medical decision but a personal one. The perception we have of ourselves defines who we are and how we introduce ourselves to the world. Breast augmentation can help individuals who feel the need to project a better outward appearance and results in increased self-esteem and personal satisfaction.

As with any surgery, there are always risks as there are with breast augmentation. When deciding on breast augmentation or any other surgery, you need to weigh the benefits and risks as well as expectations. You want to make sure you are making this decision for yourself and not for anyone else. You must realize something foreign is within your breast and that over time complications

could happen, as with any surgery.

When I approached my husband about breast augmentation he was totally supportive of my decision, knowing I had thoroughly researched the procedure and having full knowledge of what the pros and cons of the surgery could entail. I consulted with two certified plastic surgeons, both of whom were equally knowledgeable in their professions, making me feel quite secure in my decision.

After all of my research, I was made aware of the fact that my implants could rupture and may not last forever. At informational web sites, such as FDA.gov and Implantinfo.com, by Nicole, I learned that I was at risk for capsular contracture, rippling, infection and other complications. Despite these risks, I decided the benefits outweighed the disadvantages. This was a personal choice made by me and my husband, not by society governing our decision. Once all the options and any results were researched it was ultimately my decision.

I still feel the decision of breast augmentation was the right choice for me, even though it has only been one year and ten months

ago. I have no regrets and when asked would I do it again, my answer is a definite yes. Has it made me feel better about myself? Yes, in ways only a woman can feel from the inside out. Thank you.

DR. WHALEN: Thank you. Are there any questions?

[No response]

Thank you, ma'am. The next speaker, and I apologize if I mispronounce your name, is Dr. Joseph Bubinak.

DR. BUBINAK: Thank you, Mr. Chairman and all members of the advisory panel. I answer no to all four questions. I am a board-certified hematologist and medical oncologist. My undergraduate training led to degrees in mechanical engineering and science. I retired from active practice two years ago.

One year ago, a former patient with a history of ruptured breast implant and a low platelet count called and said she was told that she was, quote, full of platinum, unquote. Excessive platinum was found in skin, subcutaneous tissue, blood, urine and subsequently bone marrow. This interested me because I have treated patients with platinum-based chemotherapy since 1976. A low

platelet count is a frequent side effect. The first chemotherapy agent was cisplatin, which is also mutagenic, carcinogenic, leukemogenic and teratogenic. Platinum has been found in the milk of patients treated with platinum compounds.

There is little information in the medical literature regarding an association of platinum with breast implants. Unfortunately, not everyone has a good result. Information obtained from many sources, including interviews with patients, physicians and researchers, reveal that some implant patients develop a variety of systemic complaints including malaise, hair loss, peripheral neuropathy which is sometimes disabling, loss of short-term memory, rash and other allergic manifestations, respiratory systems, constipation and anorexia, just to name a few. In short, these are the same side effects people treated with cisplatin cytotoxic chemotherapy experience. Increased intensity of systemic complaints commonly follow gross rupture of the implant.

I was astounded to learn that the catalyst used to manufacture the silicone for silicone gel and silicone elastomer for both gel-filled and saline-filled implants was platinum chloride, a

highly reactive molecule and precursor to the chemotherapy agent cisplatin. The chemistry of the polymerization process says that the platinum in ideal proportions is reduced to its inactive elemental form. This, however, does not correlate with the amount of platinum found in tissues both proximate and distant from the implant site.

Two independent researchers now have found platinum in excessive concentration in tissues. Capsule formation around the implant, a frequent complicating event, tells the world that this device is not inert. Even without considering the seepage of low molecular weight silicones, the migration of reactive platinum alone can explain capsule formation.

One package insert states that the literature suggests that radiation therapy may increase the likelihood of capsular contracture, necrosis and extrusion. I have witnessed this first hand. In this regard, you should understand that platinum-based chemotherapy is commonly used explicitly to sensitize the target tissue to the effects of radiation therapy.

In conclusion, systemic systems do matter and must be listed as potential side effects in the

package insert when patients are expected to give informed consent. Likewise, reports of symptomatic improvement in patients following explantation must also be included. Despite almost 40 years of clinical experience, there is not one good, solid, prospective epidemiologic study available. The largest study that I saw was a retrospective study, just last year, and that study showed increased risk for respiratory and brain cancers, and a non-significant increased risk for leukemia of various types.

Milk from implanted mothers needs to be tested for bound and unbound platinum. Reliable, generally accepted methodology for determining free and bound levels of platinum in any tissue must be developed with all speed. Analysis for platinum DNA must be made available if other critical questions are to be answered. Long-term ex vivo testing of implants, subjected to realistic stresses while immersed in physiologic biologically active media at 37 degrees, are needed.

Last, from a pure engineering perspective, considering the failure and complication rates, I wonder what reasoning could have led to the approval of these devices. Reasonable assurance of

safety and effectiveness--no one would argue against the beneficial psychological effects a positive body image will give. Safety means unhurt, secure from any harm.

I urge this panel to approve only products that are truly safe and effective for all who desire them. Thank you.

DR. WHALEN: Thank you, doctor. Any questions??

[No response]

Thank you. Next, Ms. Kim Hoffman.

MS. HOFFMAN: My name is Kim Hoffman. I am a party to litigation, and my answer is no to the rest of the questions.

Ladies and gentlemen of the panel, I commend you for your due diligence in participating in this meeting and ensuring that your concerns and recommendations regarding the approval of saline breast implants are being handled appropriately. I hope my testimony today will outline the importance of your continued diligence and careful scrutiny of information that is provided to you, and perhaps you will consider that important information has been withheld from you. I am happy to provide you with supporting documents, including my testimony

before the United States Congress last November on this issue.

I am here today to get several issues on record and to make the panel aware of information which may affect your opinion of the saline implants that were approved two years ago. I am deeply concerned that a lot of essential information was withheld from the panel in 2000, and I question the accuracy of the data you did receive.

For example, Dr. Bobby Purkait, Mentor's director of research, testified to the panel about issues involving betadine use with implants. If you review his testimony and compare it to information in the 1997 FDA 483 inspection report, you will find he misrepresented the facts to you.

Furthermore, at the time this panel reviewed Mentor's PMA in March 2000, Mentor was under an open criminal investigation for allegations of serious irregularities in breast implant studies and other issues involving the integrity of Mentor and their products. Did the FDA make this panel aware of the investigation and the issues involved in the investigation? The Chairman of the House Commerce Committee felt this

important enough to write a letter to the Commissioner of FDA asking why the FDA would even proceed to panel under such circumstances.

The story broke in USA Today in March, 2000. Mentor's lead counsel made a public statement denying the issue under investigation. The false statement made by Mentor's representative caused extreme fluctuations in stock prices.

Given that Mentor lied to the public about the criminal investigation, and the investigation involves allegations of serious irregularities in breast implant studies, should this advisory panel trust the integrity of the data supplied from Mentor? Why should the FDA trust the integrity of the data? Especially since the data that was presented was problematic to begin with and because two FDA employees with knowledge of the issues involved in the criminal investigation recommended the application integrity policy.

Numerous informants have reported product defects and coverups by the company resulting in a criminal investigation that was opened nearly four years ago and remains open today. All of these issues should have been resolved and the criminal investigation concluded before this panel was asked

to review the PMA data from this company in 2000. Since that didn't happen, I wanted to make sure you were notified about this today.

Many of the allegations that were raised in the criminal investigation have implications for the safety and efficacy of breast implants. For example, fraudulent manufacturing records subvert the ability of the FDA to review certain safety issues like platinum or polyurethane contamination, and fraudulent study data subverts the ability to review efficacy.

I would like to briefly address the issue of informed consent. Unfortunately, patients have not been made aware of the numerous problems and violations of good manufacturing practices found during FDA inspections at Mentor, in addition to the violations alleged by industry insiders. In fact, FDA has been denying the public's requests for these reports when requested under the Freedom of Information Act. I hope the FDA has at least provided these inspection reports to this panel, and that in the future this panel will ask to review all FDA 483's and EIR's for a company as part of the PMA review process. It is my understanding that Mentor has had yet another bad

inspection report since the approval of saline breast implants. Again, I hope you will ask the FDA for this information.

I would like to end by reading some quotes for a deposition of Mentor's former vice president of marketing. Ms. Altavilla is talking about the difference in contracture rates between smooth and textured implants. She states that textured implants significantly reduce the capsular contracture rate, from almost 60 percent to almost five percent. However, she went on to say that the textured implants had another problem, they wrinkled 100 percent of the time with patients. My understanding is that wrinkling leads to crease-fold failure.

Does the data supplied to you indicate a 60 percent contracture rate with the use of smooth implants? In another unpublished study, done by Mentor's product evaluations department, it was found that Siltex or textured implants have a five times greater deflation rate than smooth implants. Does the data you have received reflect that? Do the consent forms?

Two years ago members of this advisory panel expressed concerns that patients need better

informed consent. Unfortunately, the panel itself did not have all the information they needed and neither do the patients. I think the panel now has to question whether the information provided by the manufacturers can be trusted, and must ask the FDA what efforts have been made to check whether the data is accurate. With all due respect, I urge you to carefully scrutinize all information received from Mentor Corporation.

At the last panel meeting, some members marvelled that women wanted breast implants despite their high complication rates. Did the panel consider that women are not clearly informed about the high complication rates? Plastic surgeons at the meeting repeatedly stated that the rupture rate was very low, despite clear research data to the contrary.

I hope you will review the material I am supplying in the form of written testimony, and I hope you will give serious consideration to the issues raised and the impact it will have on public health, not just for breast implant recipients but for their family members and the cost of medical care in this country. Thank you.

DR. WHALEN: Thank you. Any questions for

Ms. Hoffman?

[No response]

Thank you. Each of the six individuals we have heard from thus far have been representing themselves. We now proceed to various individuals who have identified that they are speaking on behalf of certain organizations. The first is Ms. Margaret Volpe, from the Y-ME National Breast Cancer Organization. Ms. Volpe?

MS. VOLPE: As you said, I am representing Y-ME National Breast Cancer Organization. Y-ME has received a minuscule amount of funding from manufacturers in the past, and the answer to the remainder of your questions is no.

Thank you for allowing me to present a statement to the advisory panel. Y-ME is committed to providing support and accurate information to empower individuals touched by breast cancer so that they can select, in conjunction with their healthcare provider, the most appropriate options for themselves, including options for breast reconstruction. Options give cancer patients some sense of control in restoring health and quality of life. Saline breast implants are an important option for women who face breast cancer.

Y-ME welcomes the additional data from the manufacturers, and hopes it will put to rest the concerns many have expressed about breast implants. I was diagnosed with breast cancer in 1995 and had a mastectomy and tissue expander. I received an implant in February, 1996. Reconstruction meant not worrying about how clothes fit; feeling whole again; not being constantly reminded of breast cancer and getting on with my life.

I have had no problems or complications with my implant since my surgery. While I was eligible for TRAM reconstruction, I didn't want to endure the major abdominal surgery and painful recovery period. I wanted to keep those muscles intact. Many women do not have this option at all. They are too thin to have the needed tissue for the TRAM reconstruction. Even the latissimus dorsi or back-flap reconstruction usually requires an implant.

If implants were not an option we would be reminded daily of the mutilation to our breasts. Each woman who has had a mastectomy must be allowed to pursue the best option for her, including breast implants. At present, a woman who has had TRAM reconstruction on one breast is unable to have a

second TRAM reconstruction at a later date if she should develop cancer in the other breast. It is imperative that we continue to have a choice, and for many of us implants are the only choice we have.

Y-ME believes the availability of saline implants is very important to women who face breast cancer. It is the only uncomplicated option left for women who desire an implant as part of their breast reconstruction after the FDA's 1992 restrictions. It was very difficult for me to get the implant I received in 1996 because of FDA restrictions that required me to be in a clinical trial.

This panel must abide by the science when evaluating saline breast implants. Do not allow yourself to get diverted and side-tracked by special interests. The National Academy of Sciences Institute of Medicine report was issued, and the science is clear. The IOM conducted an exhaustive and definitive review of all the existing research and found that there is no evidence that silicone breast implants cause cancer or disease. This report also found the same results for saline breast implants. U.S. Court's

National Science Panel and several European government scientific panels, including the U.K.'s independent review group, issued similar findings.

Y-ME emphasizes the need for a wide range of treatment options as each woman must be able to choose the option that best fulfills her needs. Y-ME worked with FDA to produce accurate information and uses the FDA and IOM breast implant information booklets when counseling women. When it comes to the implant itself, women should understand that no medical device lasts forever. Shunts, heart pacemakers, even artificial knees and joints have a limited life span and possible local complications. Women should be aware of potential rupture and the need for replacement.

Adequate informed consent is a key part of the process. Doctors should discuss risks and benefits in detail with their patients. Saline implants do have a silicone shell, but from the exhaustive research on silicone implants, pointed out by the IOM, we also know that there is no convincing evidence that silicone produces an immunologic response. The IOM states such diseases or conditions are no more common in women with breast implants than in women without breast

implants.

In closing, I urge the committee to act based on the science alone. Breast cancer is a devastating disease. In the effort to resume our lives, breast cancer survivors have the right to select appropriate and effective medical therapies or devices. Thank you very much.

DR. WHALEN: Thank you. Any questions of Ms. Volpe?

[No response]

Thank you, ma'am.

MS. VOLPE: Thank you.

DR. WHALEN: The next identified speaker was to have been Ms. Sybil Goldrich. I understand it was by a videotape and that has not been able to be arranged. Is Ms. Goldrich in the audience? If not, next then, from the Sheridan Group is Ms. Cherien Dabis.

MS. MCDONOUGH: Ms. Dabis couldn't be here today.

DR. WHALEN: You are Ms. McDonough?

MS. MCDONOUGH: I am. So, I am going to do part of her testimony and mine, if it is okay with you, and try and cover it all.

DR. WHALEN: It is just that each speaker

gets five minutes.

MS. MCDONOUGH: All right, I will do my best. The answer to your questions are all no. I actually am not representing any company, I am here on my own as well so the answer is no to all of those.

Good morning. My name is Mary McDonough, and for ten years I played Erin on the TV show, "The Waltons." After the show ended I chose to have breast implants because of the pressure I felt within my industry to look a certain way.

It is a decision I now greatly regret. Before going through the surgery I did do my homework. I talked to my friends who had had implants and I talked to my doctors, and I read the very little information that was available at the time. Years later, I now realize that I made that decision based on misinformation and I have paid for that decision, like thousands of other women, who have faced serious complications, ultimately requiring the removal of a breast implant. I had my implants in for ten years.

Like most Americans, I believed the FDA and that if a product was FDA approved or under a study, it meant every precaution had been taken to

ensure the safety and effectiveness of the product. This naivete cost me my health, if not nearly my life. I have been diagnosed with lupus. But I am not naive anymore.

Two years ago I sat in this very room and I learned that the process of the FDA that they use to approve products is fundamentally flawed. I was shocked to learn that my testimony, given on a Wednesday, was irrelevant because the decision had been made on the previous Monday. It was a mockery of the democratic process and, frankly, it made me very angry. But my anger has now turned to education and that is my purpose for why I am here today because I want to share this with you as the gatekeepers of America's health and safety, what we have learned in the past two years.

I will raise questions about the data that was used by this committee to approve those products and I will point out gross violations of the FDA's own policies that allowed this product to move forward, and I will call into question the integrity of the manufacturers who produced these products.

American women count on the FDA and the advisory committees such as this one, and to this

day the women have been poorly served on the issue of breast implants. I hope that today we can start to rectify that. Here are my three points:

First, saline implants were approved in 2000 under a cloud. Mentor Corporation had a history of violations and warning letters regarding good manufacturing practices and medical device reporting, a history that has persisted through today.

McGhan Corporation also has a long history of violations of good manufacturing practice and medical device reporting. Since 1992, the company has received numerous warning letters from the FDA for manufacturing violations that directly relate to implant safety. This information is important because it casts doubt on the integrity and legitimacy of the manufacturer's practices, including their ability to conduct valid clinical trials and, since as an advisory panel, you solely rely on data produced by the manufacturers, their credibility and reliability should be critically important to you. Yet, both of these manufacturers were approved in 2000 for saline implants without discussion of the history of the manufacturers.

The FDA has an application integrity

policy. This policy allows FDA to halt or suspend the approval process when there are significant questions regarding an applicant's data integrity, or if there are concerns regarding a manufacturer's practices. By invoking this policy, it would have been difficult, if not impossible, for these manufacturers to bring their PMA applications for approval under the FDA guidelines. I question, and perhaps you do too, why this policy was not invoked for these two manufacturers.

Second, the data regarding the reporting of adverse events is suspect. I have learned that there are serious discrepancies in Medical Device Reporting, otherwise known as MDR, for both Mentor and McGhan.

According to Mentor's 2000 PMA clearance letter from the FDA, they were required to submit MDRs under the identifier P990075 as part of the conditions of approval and postmarket surveillance. However, upon checking the reporting history, no MDR has been filed under that identifier. Mentor has filed MDRs for saline breast implant under other identifiers, however. In fact, the majority of MDRs filed by Mentor have been under identifier P940039, and that does not correspond to any

approved PMA in the FDA system.

We have found similar discrepancies with McGhan's MDR reporting as well. For example, since 1996 167 MDRs have been filed for McGhan under identifier K8810444446. This identifier is not a McGhan 510(k) number. It belongs to US Dental Corporation's Super Pik Massaging Pick for Oral Hygiene. That was submitted to the FDA in March of 1988 and was cleared in May of 1988.

Under this system of surveillance, how are we, or more importantly you, the FDA advisors, ever to get accurate information on the complications and the failure rates? Six months prior to the approval of this product, the manufacturers of these devices were given an exemption to report adverse events for saline and silicone implants not under the MDR system, but under the new alternative summary reporting system. This exemption was made despite the FDA's own policy not to use this alternative for devices that were approved less than two years. Exemptions like this are curious but they also produce dangerous results.

Looking at the data from the alternative summary reporting system during the years of 1999 to 2001, 34,356 adverse events were reported and

filed with the FDA through the ASR system for Mentor and McGhan. Of those, 30,290 are for saline implants along, 30,000 adverse consequences. I can't help but think if these were penile implants this matter would have been resolved.

Finally, the postmarketing data on saline implants--

DR. WHALEN: Ms. McDonough, you need to come to a conclusion, please.

MS. MCDONOUGH: Well, I guess you are aware of the adverse events but I just wanted to tell you that there were 30,000 adverse events reported and it just doesn't measure up with this data, and I would like you to take a look at that. It is so important for you to know so women can know all of the information. If you could read Cherien's testimony, it is very compelling and I urge you to read it. She was a 19-year old girl who got a saline implant for a defection which was a tumor in her chest. Through all the manufacturers' information she made this choice and then had a ruptured implant which caused her great pain. So, please take a look at that and please look at the data, and thank you very much for letting me talk today.

DR. WHALEN: Thank you. Are there any questions for Ms. McDonough? Dr. Miller?

DR. MILLER: Thank you for your testimony. What is the Sheridan Group?

MS. MCDONOUGH: I am here on my own today. Cherien is with the Sheridan Group. The Sheridan Group is a lobbying firm.

DR. MILLER: Thank you.

DR. WHALEN: The next speaker is Ms. Cynthia Pearson, executive director, National Women's Health Network.

MS. BARON: Ms. Pearson couldn't be here today. My name is Tonia Baron and I will be reading a statement on her behalf. I would like to start by saying that the answer to all four questions is no.

My name is Cynthia Pearson, and I am executive director of the National Women's Health Network, a non-profit, non-partisan organization that has been dedicated to improving women's health for more than 25 years.

The Network has been examining the safety of breast implants for more than a dozen years, and our primary concern has been the lack of safety information. When we first became involved in this

issue there were no studies of women in the published research literature. Although almost a million women had breast implants, no breast implant had ever been approved by the FDA.

Today, there are quite a few published studies on the safety of breast implants and saline implants made by two manufacturers have been approved by the FDA. Nevertheless, the Network remains very concerned because there have been more than 150,000 adverse reaction reports to the FDA for women with breast implants, and there are still no long-term safety studies.

This meeting provides the first opportunity to revisit the FDA's approval of saline breast implants since they were approved in 2000. The manufacturer studies were strongly criticized by the FDA's advisory committee two years ago because of the poor quality of their recommendation. One might expect that the manufacturers would have been grateful that their implants were approved despite the high complication rates and poor quality of the data and would have, therefore, made sure that their five-year studies were better designed and analyzed.

Instead, the new studies have many of the same flaws as the previous studies, and the response rate is even worse than it was at the PMA meeting in 2000. I will not go into details about the statistics because that does not seem necessary. Anyone who knows anything about research, and many who even know nothing about research, know that you can't lose 95 percent of your sample and still have a meaningful study.

When Mentor Corporation analyzed their five-year follow-up data on only 60 of the more than 1200 women who were enrolled in the augmentation study, they did a disservice to more than 400,000 women who underwent augmentation surgeries since saline implants were approved in 2000, to you, the FDA advisory committee members and to the FDA. There is no excuse for that kind of shoddy research. In fact, it does not deserve to be called research. It is meaningless data.

The fact that Mentor improved their follow-up to 24 percent at the six-year mark shows how little attention went into their five-year study. But even a 24 percent response rate is much too low to be meaningful. A response rate under 50 percent raises more questions than it can answer.

Are the other women dead or alive? Are they healthy and happy or sick and seeking medical care elsewhere? We don't know the answers to these questions so the data can't really tell us about the safety of implants.

The McGhan data are a little better. Like the Mentor study, they manipulate the data to make it seem that saline implants are safer than they really are. Both Mentor and McGhan made note of the women who had both their implants removed, but they are not included in the complication rate data. Instead, they are apparently excluded from the study as if they never existed or, worse, as if they are satisfied with their implants or have the same complication rate as everyone else.

Even with this highly inappropriate data manipulation, approximately one out of every three McGhan augmentation patients are described as undergoing additional surgical procedures, an average of more than two additional surgeries per patient.

Consumers deserve an FDA that keeps unsafe or ineffective medical devices off the market. They also deserve accurate information about the long-term safety of medical implants that are

intended for long-term use. In the case of breast implants, the manufacturers have failed to conduct meaningful long-term safety studies and, as a result, consumers are continuing to buy implants that are FDA approved but are not necessarily safe.

All we do know is that breast implants have an extremely high complication rate, higher than any medical product I can think of with the exception of a small number of life-saving products used by patients who have no other choices. Even the misrepresentation of data does not hide that fact.

On behalf of the National Women's Health Network, I strongly urge this advisory committee to speak on behalf of the millions of consumers who are not able to come to this meeting but who look to the FDA to protect them from harmful products. If this advisory committee does not vehemently criticize these studies and the manufacturers' misrepresentation of their own research and urge the FDA to take a stronger watchdog role, breast implants will never be improved and accurate and informative research will probably never be conducted.

DR. WHALEN: Thank you. Are there any

questions?

[No response]

Thank you. Next, we will hear from Dr. V. Leroy Young, from the American Society of Plastic Surgeons. Dr. Young?

DR. YOUNG: In answer to the questions, I am a practicing plastic surgeon and breast implants are part of my research and part of my income. I also receive funding from several of the manufacturers and have served as a consultant for several of the manufacturers, and my expenses to travel here were paid for by the American Society of Plastic Surgeons. I am not involved in any litigation.

What I would like to do with the time that I have is present work that the American Society of Plastic Surgeons and the work of the Plastic Surgery Educational Foundation has either conducted or funded to try to understand the performance of breast implants and the risks and benefits that patients derive from them.

I have provided a written copy of the slides which we have here, and I will tell you that we have a lot more information available that we would be glad to share with you but, because of the

limited time, we couldn't put all of that into a presentation. I apologize that this is taking so long.

DR. WHALEN: You might want to start with your remarks because the clock is ticking away.

DR. YOUNG: Well, what I want to emphasize about this is that our organizations are primarily interested in patient advocacy, research and education. We have made a real effort to improve patient advocacy in the last two years by initiating a national breast implant registry. This was done by Plastic Surgery Educational Foundation because we felt that it was the right thing to do for patients. We also felt, because there have been lots of concerns, some of which we have heard today about the quality of research, that there should be independent data that is not sponsored by the manufacturers available for patients and for surgeons. This registry provides a source of that data, and it provides it in an ongoing, timely fashion and we publish it on a regular basis.

This registry, as I said, was founded in July of 2000. At the present time we have almost 4000 patients enrolled in it. From this, we are

learning things about the incisions that are used to insert the implants, the type of implants that are being used, the position they are placed in but, more importantly, I think we are learning a lot about why reoperations occur and how often they occur. From that, we are implementing steps to try to decrease the reoperation rate.

In May of this year we also began an international registry that includes most of the countries in Europe and South America, and we feel that this is important because this is going to let us accrue data more rapidly. It will let us make comparisons of different groups of surgeons, and it will let us learn about different types of implants.

We are also working on informed consent, and we are working on that in two ways, by administering a survey in surgeons' offices and by posting the survey on the implant info web site. The beauty of this is that it allows women to comment either positively or negatively about their results and they are not under the influence of the surgeon's office when they do that. It is a detailed questionnaire that goes over preoperative, postoperative and pre-operation data. From this,

just as examples, we are learning how the size of the implant was chosen and what we have seen from that is that today's patients are much better educated. They are taking an active role in their medical care. As you can see from the slides I provided you, the surgeon and the patient decide together about size in 81 percent of the cases.

We are also trying to survey how responsive surgeons are to patients. From that, we have provided you data that 79 percent of the surgeons prepared the patient for what to expect, and 83 percent took time to answer the questions the patient was interested in.

We are also trying to assess did surgeons inform the patients about the potential risks. We have heard criticism of that today, and you can see that we are getting good data on that and that the majority of surgeons are apparently informing patients of most of the risk, but we need to work harder to get this to be 100 percent rather than 70-80 percent.

We are also getting data on the impact on life and we can see that there are several positive impacts from that. One of the big issues at the last panel meeting was related to pain. One of the

things we have done is show, in a survey, that a significant number of women who don't have implants have pain, approximately 48 percent. We have also looked at the pattern of pain and how implants affect it. From this survey, it appears that implants don't affect the pattern of pain but in a small percentage, 13-15 percent, it is more severe and it occurs more frequently. So, breast implants do have an effect on that.

Another issue was nursing. We have seen from the survey that about equal numbers of patients had children and had a history of nursing before and after augmentation. The problems that occurred with nursing were similar in the two groups of patients but they did not appear to be any worse in the patients who nursed after augmentation. So, we are getting a lot of useful information from this.

One of our main concerns is the report in the literature that one in five women who has an augmentation has a second operation within five years. We are trying to decrease that and learn if that is really true. We have done one study, which we have just completed, which shows that if you apply the principles that we have learned as a

result of these studies that I am mentioning, we can at least cut this rate to ten percent, and we think we can decrease it even further.

Furthermore, we are funding research all over the world. We have two studies in Finland now on rupture and local complication, and we are looking at the frequency of etiology of reoperations, as I said. We have just completed a betadine implant related study, and we have funded a Center for Device Retrieval Analysis which focuses on breast implants.

PSEF and ASPS are committed to the patients and we are committed to understanding these things, and I will be glad to try to answer any questions you may have.

DR. WHALEN: Thank you, Dr. Young. Is PSEF separately incorporated?

DR. YOUNG: Yes.

DR. WHALEN: Does it receive any grants or funding from the manufacturers of saline breast implants?

DR. YOUNG: It has in the past, yes, indirect funding.

DR. WHALEN: Do you have any idea what the dollar amount of that is?

DR. YOUNG: Early in the '90's I think there was altogether about six million dollars. That amount has remained constant over the past ten years or so, other than the funding that we received for the betadine study which was about $30,000.

DR. WHALEN: Thank you. Are there other questions for Dr. Young? Yes, Dr. Dubler?

DR. DUBLER: Thank you very much for your presentation. I have a question. Do you and members of your organization advertise about breast enhancement?

DR. YOUNG: Yes.

DR. DUBLER: You do? And what is the goal of that advertisement?

DR. YOUNG: I think in most instances it is to encourage people to inquire about it.

DR. DUBLER: To inquire about it, and maybe to go ahead?

DR. YOUNG: If it is appropriate for them, yes.

DR. DUBLER: And, what would you say the goal of an informed consent process is?

DR. YOUNG: To educate the patient sufficiently that they understand the risks and the

benefits of the procedure or treatment so that they can make a decision that is appropriate for them.

DR. DUBLER: So, that sounds like an even-handed process.

DR. YOUNG: Yes.

DR. DUBLER: Is advertising and marketing an even-handed process?

DR. YOUNG: No.

DR. DUBLER: Can a person who does one do the other equally well?

DR. YOUNG: I believe so.

DR. DUBLER: Thank you.

DR. WHALEN: Other questions of Dr. Young?

[No response]

Thank you. Next, we are to hear from Dr. Laurie Casas, from the American Society for Aesthetic Plastic Surgery. Dr. Casas?

DR. CASAS: Thank you. First I will answer your four questions. I am a board-certified plastic surgeon and have been in clinical practice for 12 years. I have managed hundreds of patients with breast implants and, therefore, a portion of my income is derived from breast implant surgery. My travel expenses to this hearing were paid for by the American Society for Aesthetic Plastic Surgery.

I am currently chair of the Society's communications commission. I have no financial ties to any implant manufacturer. I am neither a witness nor a party in a pending lawsuit related to breast implants.

I am here today on behalf of the many thousands of patients who tell us that breast implants have made a positive difference in their lives. I am associate professor of surgery at Northwestern University Medical School. I have co-authored a book on breast surgery, and am currently a participant in a multi-site investigation of patient satisfaction following cosmetic procedures.

Given the proven level of safety and efficacy of breast implants, the American Society for Aesthetic Plastic surgery is in full support of the FDA's approval of these devices, along with the FDA's continued oversight. Members of ASAPS, who are all board-certified plastic surgeons, welcome this oversight for two reasons:

First, to ensure that the collection of data on breast implants is ongoing and, second, that women considering the procedure have the benefit of the most current information.

Part of ASAP's mission is to provide accurate information to the public. We do this directly through our web site, and also through our members via patient education and informed consent.

Informed consent occurs when patients are provided with all the facts and information necessary to make an educated decision to proceed with a medical treatment or surgical procedure. Full informed consent is in the best interests of both patients and physicians.

ASAP's members are patient advocates. We feel that patient education, safety and satisfaction are of primary importance. We believe strongly that a woman's right to choose breast implants is paralleled by her right to be fully informed about the risks and the benefits.

The Society offers continuing education to its members, providing information to assist them in evaluating and judging the appropriateness of their patients' motivations and expectations. Therefore, we believe that patients with inappropriate motivation or expectations should be counseled against surgery.

There is a growing body of evidence that suggests that cosmetic surgeries, such as breast

augmentation, lead to improvement in at least three areas of psychological functioning: body image, quality of life and depressive systems.

The research arm of the Society, the Aesthetic Surgery Education and Research Foundation, has recently funded a multi-site outcome study on patient satisfaction following aesthetic surgery. This study will provide additional important data on that critical subject.

An increasing number of women today are choosing breast augmentation to enhance their appearance, over a million women in the past decade alone. Most women seeking breast augmentation come to plastic surgeons for two principal reasons.

The first is a woman who finds that her once normal breasts have lost considerable volume following pregnancy and lactation and are not in proportion to the rest of her body. The second reason a woman comes to us for breast augmentation is if she has grown to adulthood with no breast development. She feels her breasts are out of proportion.

The change in how she feels about herself after surgery is dramatic. I have seen lives transformed by breast augmentation. The typical

breast augmentation is usually a woman in her 30's, most often she is married and has children. She is a responsible adult with a family, career and normal life.

Women have to overcome tremendous obstacles to have breast augmentation, from societal prejudice to a wealth of misinformation. The fact that so many seek it out speaks to its strong desire. Satisfied patients have created the popularity of this procedure, and research has shown that the vast majority of women who have breast augmentation would make the same choice again.

The high satisfaction rate, and the determination of so many women to undergo a surgery with the knowledge that it is not a perfect operation, suggests just how deeply the benefits are felt.

Members of ASAPS believe it is our responsibility as health professionals to provide accurate and up-to-date information by which a patient can exercise her right to informed consent. We welcome the opportunity to work with the FDA and within the FDA guidelines to achieve this goal.

The American Society for Aesthetic Plastic

Surgery, and its 2800 board-certified plastic surgeon members and candidates, are committed to this process.

DR. WHALEN: Thank you. Any questions for Dr. Casas? Dr. Dubler?

DR. DUBLER: Thank you very much for your testimony. Do you advertise?

DR. CASAS: No.

DR. DUBLER: Do your colleagues in your organization advertise?

DR. CASAS: Yes.

DR. DUBLER: Why don't you?

DR. CASAS: I have never had the need to. I have a very busy practice and for me, personally, the value of spending the money to market is not obvious to me; I don't see a value.

DR. DUBLER: Are there any commonly done plastic surgery interventions which you don't do because you think they are not for the benefit of patients?

DR. CASAS: You have to be more specific. I am not sure what you are asking.

DR. DUBLER: Liposuction?

DR. CASAS: Could you rephrase the question?

DR. DUBLER: Are there any commonly done plastic surgery interventions which are not part of your common practice because you think they are not for the benefit of patients?

DR. CASAS: Interventions typically mean you are intervening with a past procedure.

DR. DUBLER: I am sorry, surgical interventions.

DR. CASAS: Well, surgical procedures, are there any surgical procedures that I don't perform?

DR. DUBLER: Correct.

DR. CASAS: Why?

DR. DUBLER: Because you think they generally don't help patients, are not in the interest of most patients; the data don't support their effectiveness.

DR. CASAS: You are asking a question that can't really be answered. I mean, there are thousands of different procedures that we can perform as plastic surgeons to mold and reshape the body, and we don't have a list. You know, there are pros and cons for every different procedure and you individualize with each patient. So, it is not like general surgery where you have hernia repair, gallbladder--you know, a list. We have thousands

of procedures that we perform, small, large, somewhere in between, and we individualize.

DR. DUBLER: You said that patients with inappropriate expectations are discouraged from having surgery. Why?

DR. CASAS: Because the most important interface that we have with the patient is the process of informed consent. So, it is our job and our duty to prepare patients for procedures. The interview process is very straightforward. The patient presents with a particular body part they are not satisfied with. We talk to them about their motivation, their present health status, and then provide them with alternatives. On that list of alternatives is not to do a procedure, and that is part of the informed consent. So, if in the process of informed consent, as a physician, we feel that the motivation is inappropriate, their health status is not adequate, we would counsel them against the procedure.

DR. DUBLER: Are you aware that some of the more recent studies on informed consent, the empirical studies, show that patients in general think that the informed consent process is to protect the doctor and the institution, not really

to inform them?

DR. CASAS: I am not aware of those studies.

DR. DUBLER: Thank you.

DR. CHANG: Dr. Casas, I have a question that may be a little difficult to answer, but if in the informed consent process, let's say in the patient brochure, or if every plastic surgeon doing the counseling, came right up front and said early data from manufacturers suggests that three to five percent of these implants may fail within three years, or that one out of five patients may require a reoperation, in your opinion would the rate of breast augmentation stay the same, or might it go down?

DR. CASAS: It is an interesting question because those are the statistics I give patients and they still want breast augmentation and breast reconstruction with implants. I think women are looking for a choice in changing their body structure, and for the breast we either have implants or your own tissue, or a combination of the two. So, we are limited by the choices. So, I think patients evaluate always the pros and cons of all their choices, at least in my office and my

practice, and I think ASAPS does that and teaches that in a very, very straightforward way. There is absolutely no opportunity in our minds that a patient chooses an operation without full informed consent. It is critical in the process.

DR. CHANG: Thank you.

DR. WHALEN: Thank you. The next two speakers that have been identified to us are both from WIN Against Breast Cancer, Ms. Mullen and Ms. Crigler. As I understand it, Ms. Mullen is not going to be present and Mr. Crigler was to read her statement. What I am going to ask is that Ms. Crigler go ahead with her own remarks at this juncture and then, at a later point in time I will call her back, as time allows, to read Ms. Mullen's statement. Ms. Crigler?

MS. CRIGLER: Good morning. My name is Sheila Crigler, and I am truly blessed to be here today to present my perspective on saline-filled breast implants. I am in no way receiving financial compensation from any implant manufacturer, nor do I have a pending lawsuit.

I am here as an official person for Women's Information Network Against Breast Cancer, the acronym being WIN. It is a national non-profit

organization, founded by president and CEO Betsy Mullen. Other hats I wear, I co-facilitate Women Reaching Women, a support group for breast cancer survivors. Not only do I hope to speak as an advocate, but mainly as a breast cancer survivor with saline-filled breast implants.

Most of us have heard that life begins at 50. A few weeks after turning 50, I received a telephone call from my surgeon at that time regarding my recent mammogram. To him, it was a routine telephone call, but telling someone you have breast cancer over the telephone is anything but to the person on the other end. Life begins.

There were tons of information to plow through; decisions to be made. Would I live or die? Intraductal carcinoma in situ, the medical jargon; milk ducts clogged with cancer, the layman's jargon. My only option was a complete mastectomy. A woman never considers the possibility of losing a breast--more decisions and possible choices. A realization was that breasts do not define Sheila but breasts do give Sheila definition.

A consultation with a plastic surgeon brought sunshine to a dim horizon. I was a good

candidate for reconstructive surgery with saline-filled implants. More choices. For symmetry, I opted for the removal of the remaining healthy breast. This was a very personal decision and it is not for everyone. If I could prevent the possibility or probability of breast cancer in the remaining breast, it was worth it to me to give up my other breast.

The operation was a success, and the real blessing came when it was learned there wasn't any involvement in my lymph nodes. That meant no chemotherapy or radiation. My breasts were gone but I got to keep my hair.

It was over a year from the cancer surgery before reconstruction would begin. I was amazed to learn some survivors cannot look at themselves in the mirror after surgery. Imagine a billboard, as I called it, in place of mounds that once defined womanhood.

There are different types of reconstructive surgery, with saline-filled breast implants being one of the least complicated in regards to length of surgery and recovery. If a rupture were to occur, the body will absorb the saline and release it out of the body. The lack of

choices is what creates problems.

Women need the opportunity to make informed decisions. There is no one particular thing that works for everybody. Choices again. A few with strong issues against a situation should never be the deciding factor for the masses. The need is to inform consumers and not remove choices.

My reconstructive surgery was a success and my saline-filled breast implants are truly a part of my body by now. It has been almost six years since my permanent implants were put in place. That has created a completion of a circle. I began with breasts and have ended with breasts. Now I can smile at a newly diagnosed patient and show them that this is the face of cancer. I can proudly display my saline-filled breast implants that say that there is hope.

It would definitely be a travesty if this particular choice were removed. Hope is what a person does not have when she tells you she would rather die than have her breasts removed. We did not choose to have breast cancer but we can choose to have reconstruction. A woman's right to choose is what is at stake here today. I feel so strongly about this issue that I left my mother, who is

hospitalized in Los Angeles, to make the trip here to express my concerns regarding the ongoing study of saline-filled breast implants. Thank you. Are there any questions?

DR. WHALEN: Thank you, Ms. Crigler.

MS. CRIGLER: Thank you.

DR. WHALEN: Next is Dr. Diana Zuckerman, from the National Center for Policy Research for Women and Families.

DR. ZUCKERMAN: Thank you. The answer to the four questions is no, and I donated my time to be here today and traveled in my own car.

My name is Dr. Diana Zuckerman, and I am president of the National Center for Policy Research for Women and Families, which is a non-profit, research-based organization that explains medical and scientific information so that it can be used to improve the health and well being of women, children and families.

Our research center works on a wide range of health issues, with particular attention to the safety of medical products. Unfortunately, as the new research on hormonal replacement therapy has reminded us, manufacturers' claims about medical products are not always supported by research. Our

goal is to balance the hype by scrutinizing the research and determining the facts, whatever they might be.

In the case of breast implants, the more than 150,000 adverse reactions that have been reported to the FDA are inconsistent with the manufacturers' claims that implants are very safe and that implant patients are so satisfied that even when their implants break all they want to do is replace them with a larger size. So, we have used our expertise in epidemiology, biostatistics and public health to carefully scrutinize the research.

I was at the FDA advisory committee meeting when saline implants were approved in 2000. For those of you who weren't here, I want you to know that the advisory committee expressed a great deal of concern about the extremely poor quality of the research and about the exceedingly high complication rates. And, I was here to hear the shocked gasps in the audience when the advisory committee voted to recommend approval despite their very strongly expressed concerns.

The advisory committee recommended approval with the caveat that long-term safety data

and better studies be required of the manufacturers. I am sorry that many of those members are not here today because I think they would be very disappointed that the manufacturers made many of the same mistakes or misrepresentations in their data this time that they were criticized for two years ago. In fact, as a former college professor, and I used to teach research methods and statistics courses, I would have to say I would flunk anybody who would provide a statistical analysis like some of the ones that I saw in these studies.

I want to use the words of former members of this advisory committee as well as other statisticians. Since we haven't had the opportunity to hear the data yet this morning, having our public comment before it is presented, I wanted to use some of their own words to criticize these studies that you are going to be discussing today. For example, Dr. Brent Blumenstein, who was the statistician on the advisory committee last time, clearly stated that the McGhan presentations did not meet the standards of "good, peer-reviewed articles" and specifically stated that--I love this one--"accuracy is not manifest in the presentation

of the data."

The FDA statistician, Telba Irony, specifically criticized using Kaplan-Meier analyses when so many women are lost to follow-up and the researchers don't know if those who dropped out are similar to those who are in the study.

Both these statisticians criticized the large number of patients who were lost to follow-up in the studies two years ago. Of course, the new data presented today show even more women lost to follow-up.

In the Mentor study two years ago, Dr. Blumenstein criticized the company for taking patients out of the analysis if they had their implants removed. He said, "this is an extreme limitation and misrepresents the data." He then concluded by saying, "I cannot accept the accuracy of any of the data here because of the limitations I'm pointing out. I cannot feel good about any of the data presented with respect to accuracy and giving that information to an individual patient and having that patient understand what the real risks are."

Phyllis Silverman, who was the FDA statistician two years ago, stated that, "because

of the approximately 50 percent loss to follow-up with the large, simple trial, the ability to draw meaningful conclusions from this trial is limited." I fully agree with those statements, and it is obviously even worse for the new Mentor data which actually had 95 percent--95 percent loss to follow-up at five years, and 76 percent loss to follow-up at six years. Even if the rates continue to get a little higher, and I see that Mentor has made some efforts to do so, a response rate under 50 percent cannot provide useful safety data.

DR. WHALEN: Dr. Zuckerman, can you come to conclusion?

DR. ZUCKERMAN: Yes, I will speed up but I guess I would respectfully request that I get as much time--

DR. WHALEN: I am sorry, we need to have you conclude. Everybody gets their five minutes.

DR. ZUCKERMAN: Yes. I will just address what Dr. Dubler said, wondering why the manufacturers were unable to afford good researchers to do the research when they have, in fact, spent millions of dollars to advertise in every major woman's magazine, including those read by millions of teenagers.

I have here a letter that was written by two congressmen yesterday, asking that members of this committee be given information about two things, the National Cancer Institute studies on breast implants and I happen to be on the advisory committee for those NCI studies, and also ask that you be informed of the criminal investigation and problems with inspection reports.

So, I would just turn to you and say, and I will give you a copy of that letter, as an advisory committee, if you don't insist on better long-term research and on accurate reporting of that research, teenagers and women will continue to incorrectly assume that breast implants are proven safe for long-term use. I am not questioning women's rights to make choices about their own bodies, but I am questioning whether they can make an informed decision when there is no really well-conducted safety research. Are there any questions?

DR. WHALEN: Dr. Dubler?

DR. DUBLER: Have you reviewed the materials which surgeons use to discuss with patients whether to go ahead with implant surgery?

DR. ZUCKERMAN: Yes, and of course they

vary a great deal. One of the problems, as you mentioned earlier, is that so many patients think that even very clear warnings are really meant for liability reasons, not to protect them, not to provide information to them. But we also know that sometimes doctors give a written informed consent but what they say to the patient is, you know, of course, I wouldn't be doing this if I didn't think it was safe for you; my experience is that patients love their implants and most of my patients are very satisfied. So, I think informed consent, as we know, is a written version and then there is the oral version and they can be quite different.

DR. DUBLER: Do you think it would be possible, based on your reading of the data that have been produced, to devise an independent, interactive, video-based informed consent process that really permitted a woman to scrutinize the data from the perspective of the skeptical, not the supportive? Would that be a possible process to design?

DR. ZUCKERMAN: I think so. I mean, we know that there are limitations of informed consent but we have to do a better job than we are doing now. I think that your suggestion is an excellent

one because I think if there was an independent one, particularly if it was a videotape, interesting and not these terribly long, boring informed consent things that many people don't read or don't understand or don't know what to do with, I think that could really make a difference.

I have no doubt that plastic surgeons do warn their patients about some of the risks, and I guess my concern is that if they are warning about capsular contracture, but they if are not mentioning last year's National Cancer Institute study showing an increased rate of cancers and deaths from certain cancers and respiratory diseases among women with saline and silicone breast implants, then I really question whether they are getting informed consent currently.

DR. DUBLER: Thank you.

DR. WHALEN: Thank you.

DR. ZUCKERMAN: Yes.

DR. WHALEN: Next is Dr. Jae Hong Lee, also from the National Center for Policy Research for Women and Families.

DR. LEE: Good morning. I am Dr. Jae Hong Lee, a physician and the senior medical policy analyst at the National Center for Policy Research

for Women and Families. My response to all four questions is no.

The Institute of Medicine report on breast implant safety identified reoperations and local complications as the primary safety issue with silicone breast implants.

In light of the serious concern regarding reoperations and local complications, the post-approval studies recently released by Inamed and Mentor are extremely disappointing. Both studies are poorly designed and executed, and most likely underestimate the cumulative incidence of complications.

I will discuss just a few of the more glaring weaknesses of both studies. A major problem shared by both the Inamed and Mentor studies is the exclusion of patients who have had all their breast implants removed prior to the three- or five-year study interval. One can argue that these patients, among the earliest to have all their implants removed, are the most important group of patients to study. They certainly should be counted as women with complications.

Excluding data from these patients introduces an unacceptable post-entry exclusion

bias into both studies. Since it seems likely that these patients were experiencing complications rates higher than those who did not have all their implants removed, the overall effect of this exclusion bias will be to seriously underestimate the cumulative incidence of complications.

Exclusion of these patients also invalidates the Kaplan-Meier risk estimates reported in both studies. One essential condition for using the Kaplan-Meier method is the assumption of independence between censoring and outcome. In other words, one must assume that the rate of local complications and reoperations in the excluded patients was similar to those who remained in the study. Since the excluded patients had all of their initial implants removed for one reason or another, most likely due to complications, this is not a reasonable assumption to make. Using the Kaplan-Meier method in this situation clearly results in an underestimation of the cumulative complication rate, a fundamental flaw in both studies.

The problem is compounded when the reports continue to cite the full number of enrolled patients when discussing specific complications.

For example, the Inamed study enrolled 237 reconstruction patients but excluded 97 patients by year five, for an actual follow-up of only 140 patients. Inamed then reports reoperations in 100 of the 237 patients over the five years of follow-up. The question is whey were the excluded patients counted in the follow-up cohort? Is the percentage of patients with reoperations 100 out of 237, or 42 percent, or is it actually 100 out of 140? In contrast, Inamed conveniently excludes the breast implant removal patients when calculating their follow-up rate for reconstruction patients. They calculated an expected follow-up cohort of 175 by excluding 11 patients who had died and 51 patients who had all their initial implants removed. As a result, their follow-up rate of reconstruction patients was reported as 80 percent, or 140 out of 175 patients.

As mentioned earlier, it is highly inappropriate to exclude those implant-removal patients from the study cohort. If those patients are left in, the expected follow-up cohort consists of 226 patients, not 175, and the actual follow-up rate for reconstruction patients is then a clearly inadequate 62 percent.

There are also signs that the Inamed study is statistically underpowered. For example, Inamed suggests that because most of the confidence intervals between five-year and three-year risk rates for complications overlap, the true rates may not be higher at five years. They imply that it may not be necessary to follow complications with overlapping three- and five-year confidence intervals in subsequent years.

A more reasonable interpretation of this data is that the study is too small and underpowered. Since even a small difference of three percent represents over 6000 breast augmentation patients, the post-approval studies must be large enough to detect even small differences in risk rates.

As bad as the Inamed study is, the Mentor study is even worse. The Mentor report acknowledges that low response rate and the differences between the responders and the non-responders is a major limitation of their study. I would go further and state that most of the data presented in the Mentor study is scientifically worthless due to the disturbingly low follow-up rates.

Setting aside for the moment the very serious methodological problems of both studies, we find little comfort in the reported data. Even taken at face value, the complication rates are unacceptably high. For instance, Inamed reports five-year reoperation rates of 26 percent for augmentation patients and nearly 45 percent for reconstruction patients. As a physician, I find these complication rates to be completely unjustifiable for a purely elective cosmetic procedure.

The poor quality of the studies clearly indicates that both Inamed and Mentor have failed to fulfill all the conditions of their premarket approval agreement. Furthermore, the reported complication rates in both studies reinforce the Institute of Medicine's concern about local complications and reoperations. These companies seemingly lack the motivation to perform adequate and appropriate safety studies as long as they can market and sell their products as FDA approved.

So, what should be done? At the very least, the FDA should require a black box warning on all advertisements noting that the manufacturer has not adequately completed required five-year

safety studies. The panel should also recommend that patient consent forms include a statement noting the lack of reliable long-term safety data. Another option would be to temporarily suspend general distribution of these implants until better safety data become available.

The Inamed and Mentor studies leave many questions unanswered, but do make clear one important fact, right now, today, there are no adequate data demonstrating the safety of saline breast implants. Thank you.

DR. WHALEN: Any questions of Dr. Lee?

[No response]

Thank you. Next, we have Dr. Susan Pope Helman on behalf of herself.

DR. HELMAN: Those handouts are a little more detailed than what I am going to say. I am shaking, sorry. Good morning. I am Susan Helman. I live in Vero Beach, Florida. My reason for being here is to enlighten the FDA's General and Plastic Surgery Devices Panel regarding the use of non-organic platinum in the manufacturing of saline and silicone medical devices and how I have been affected.

I will be brief.

DR. WHALEN: I am sorry, I don't mean to exacerbate--

MS. HELMAN: I am sorry, the answer to all those questions is no.

DR. WHALEN: Thank you.

MS. HELMAN: Your handouts include the specific terms and means by which my body specimens were tested. I received breast implants in 1990 and had them removed in 1992, less than two years. Nine years later, in May of 2001, samples of my hair, fingernails, toenails, urine, blood, sweat, skin cells and my left axilla lymph node were obtained by ExperTox Forensic Toxicology Laboratories in Houston, Texas for analysis.

On August 15th, 2001, a bone marrow biopsy was obtained and sent out to ExperTox for during a surgical procedure to remove a residual silicone capsule remaining in my left breast and lymph nodes in both breasts, thoracic area, neck and under my right arm. Samples of these tissues were sent to the University of Florida Diagnostic Laboratories. The findings from the University of Florida were, one, foreign material through all layers of specimens; two, residual silicone adhesive; three, foreign body giant cells and vacuolated histocytes

containing silicone and polyurethane foam; and, four, silicone granuloma.

The results from ExperTox Forensic Laboratories are as follows: whole blood platinum 1542 pmo 1/L. I don't know what these things mean. I just know that the level of platinum in a human body should be no more than zero. So, I am just going to give you the numbers, if that is okay. Whole blood platinum, 1542; urine platinum 0.38; hair platinum, 1.59; nail platinum, 2.88; sweat platinum 3.85; bone marrow platinum 181.6 upper ug/L. The oxidation states of the excised nodule under the right arm were 2+, equaling 42 percent and 4+ equaling 58 percent. I just had another bone marrow biopsy taken two weeks ago. I got the results yesterday and the number is 325. So, it has gone up from 185.6 to 325.

In a comparison between this form of platinum and the known platinum containing chemotherapeutic agent cisplatin, it is known that cisplatin has a cytotoxic and neurologic action on the body and is an organic form of a platinum molecule whose properties are less toxic than the free form found in my body.

Skin cells from my cheek were also taken

for analysis and were exposed to the platinum taken out of my body, my own skin cells were exposed to platinum taken from my body and the results obtained clearly demonstrated acute, significant toxic changes such as vacuolation and cell degeneration, and conclusively established that I have sustained chronic toxic cellular injury with platinum presently disseminated through my entire fluids and tissues.

I can only speak for myself, but I am an example. This is how I have been affected and how my body has been affected. My body is basically killing itself. There are many women, breast implanted women like me in these United States with debilitating illnesses and extreme challenges too numerous to even list, but what we would ask is that the FDA panel be thorough in your understanding of the manufacture and use of saline breast implants since it is my understanding after all this that the bags used in these devices contain platinum. Thank you so much.

DR. WHALEN: Dr. Helman, it has been ten years since your implants were removed? Is that correct?

DR. HELMAN: That is correct.

DR. WHALEN: And, you said in your testimony that at two recent points in time there was a rather dramatic increase?

DR. HELMAN: That is correct.

DR. WHALEN: Has any healthcare provider that you have interacted with suggested, in view of that data ten years after these were removed, that some alternative source of platinum than the breast implants might be affecting you?

DR. HELMAN: They said only if I worked in the platinum jewelry manufacturing industry or as a motorway, like a turnpike person that takes money on the turnpike, or pump gasoline would I even have a trace of platinum in my tissues.

DR. WHALEN: But, I mean, a dramatic increase at two points in time.

DR. HELMAN: I asked the toxicologist about it yesterday morning when he gave me my new numbers, and he said it is possible that the platinum molecules relocated after the removal of the residual capsule that was left in my body. He said, because the original bone marrow biopsy was done on August 15 of last year and then, of course, just two weeks ago, he said it may have relocated. But I am going to be tested again in six months.

DR. WHALEN: May I ask what your doctorate is in?

DR. HELMAN: Metaphysics.

DR. WHALEN: Are there other questions? Dr. Doyle?

DR. DOYLE: The question of timing, you said the residual implant was removed when?

DR. HELMAN: Last August.

DR. DOYLE: Thank you.

DR. HELMAN: Yes, ma'am.

DR. WHALEN: Dr. Miller?

DR. MILLER: Thanks for your testimony. Can you tell me about ExperTox? How did you select ExperTox in Houston as a place to have your toxicology done?

DR. HELMAN: I read a paper that was produced by Dr. Lakissa, along with a few other physicians, back in '99 or 2000 and I phoned him and asked him if he would consider doing a toxicological study on me because I was sick. I was really sick and I didn't know why.

DR. MILLER: Are services like this not readily available where you live?

DR. HELMAN: No, they aren't. It is my understanding that mass spectroscopy--I have

trouble pronouncing these things--and special equipment is not readily available. I think there are a few pieces of this equipment throughout the country but they are kind of sparsely located.

DR. MILLER: Thank you.

DR. WHALEN: Thank you, Dr. Helman.

DR. HELMAN: Thank you.

DR. WHALEN: I would like to ask if Ms. Crigler would like to return to read for the record Ms. Mullen's statement.

MS. CRIGLER: The statement that I have for Ms. Mullen is the statement from March of 2000, which I am sure anyone here may not remember. It would be repetitious. Ms. Mullen was just saying that I could take full ten minutes just for expedience sake.

Basically, her statement is mainly as mine in that the saline implants gave her quality of life. At that time, Ms. Mullen had immediate reconstructive surgery and she, as I, feels that it is really a quality of life issue for a cancer patient, much different than an augmentation that someone would request for body enhancement which, as with any procedure, people have used to excess as far as the augmentation. That is my perception.

But for a cancer patient, we offer a different view as this gives us a different perspective on life.

As I stated, when women cannot even look at themselves in the mirror because of the mutilation with breast cancer, Dr. Susan Love has quoted the only cure is slash, burn or poison. They slash our bodies to remove the breast. They poison our bodies with chemotherapy and they burn them with radiation. After a woman has gone through any or all of these devastating treatments you are looking at an end result as to what she did not choose.

The choice comes with an implant for reconstructive surgery. This gives a woman a different view of life. She can feel whole again. I am sure people have noticed, whether you or anyone on the panel has done it, when people observe a female, most times the concentration is on their breast for whatever reason. Women feel whole with breast. For some women it is a dire need. As we explained, most clothing is designed by men for women, but it includes some space for breast, whatever size.

I feel that it would really be unacceptable if the study is not continued to give

women this option for whatever quality of life the woman may need at that time. Just have the choice available.

DR. WHALEN: Excepting, of course, the travel question, do you have any idea of Ms. Mullen's potential responses to the other areas that are asked of all speakers? Is there any conflict? Is she involved in lawsuits? Is she paid by any company that is interested?

MS. CRIGLER: No, she is not involved in a lawsuit or witness. It is in her statement. She is founder, CEO and president of WIN ABC, which is the Women's Information Network Against Breast Cancer.

DR. WHALEN: Thank you. Any other questions?

[N response]

DR. WHALEN: Thank you.

MS. CRIGLER: Thank you.

DR. WHALEN: If Ms. McDonough is still present in the room and if she wishes to read for the record Ms. Dabis' statement, and if she can also begin, if you know it, with what Ms. Dabis' answers would be with lobbying companies she works for, and the like.

MS. MCDONOUGH: She doesn't work for a lobbying company.

DR. WHALEN: Oh, I am sorry, I thought you said that in response to a question.

MS. MCDONOUGH: No, my response to the question was that I came here by myself and I was reading my own testimony, as is true with Cherien. If she had been here this morning, she would have been here on her own and by herself.

DR. WHALEN: So, the Sheridan Group has nothing to do with either of you?

MS. MCDONOUGH: That is correct.

DR. WHALEN: Thank you.

MS. MCDONOUGH: That is correct. Thank you for clarifying that. To the best of my knowledge, all of the answers to the questions, the four of them, are no.

My name is Cherien Dabis. I wanted to be here today to present to you information for women who have receive and will ever receive saline breast implants.

I was born with cystic hygroma, a rare benign tumor of the skin consisting of a collection of abnormal lymph vessels. At birth, a tumor the size of a grapefruit was perched on the left side

of my neck and interwoven with the delicate nerves and blood vessels in my neck, chest, arm and underarm. A series of surgeries at birth removed the growth, but also necessitated the removal of surrounding tissue, skin and muscle, leaving me with excess scar tissue and half a pectoral muscle. The scar tissue hindered the range of motion of my left arm. As I developed, the asymmetry of my chest became more and more apparent. My left breast was significantly smaller than my right. What I saw as a deformity led me to hate my body. So, I decided that when I was old enough I would pursue reconstructive surgery.

At age 18 I underwent tissue expansion, followed by stage-two reconstruction with breast implants at Christ Hospital in Cincinnati. My plastic surgeon recommended silicone gel implants, but I had done my homework. I read about the problems women had with silicone implants which, in 1992, led the FDA to restrict their use, ironically, making silicone implants only available to women who were born with defects or those having undergone mastectomies.

I assured my doctor that I did not want silicone implants. He discounted my concern, but

told me that the saline implants were a safer option. If it leaks, he said, it is only salt water. It will dissolve, leave your body and you will be unharmed. But chances are that it won't leak. It will last forever unless you suffer some major trauma to your chest, such as a car accident. My doctor tried to convince me to have both of my breasts implanted. I refused. I simply wanted to correct my defect.

In Mary of '96, my chest was implanted with a McGhan style 168 saline-filled breast implant. Another custom-made implant was inserted in my arm to fill the cavity that resulted from my birth defect. I thought at the time this implant was also saline-filled.

Nearly four years later I began to experience periodic pain and burning in my chest and arm. The burning and pain eventually worsened and my left arm became more and more immobile. I knew something was seriously wrong. I was experiencing painful capsular contracture. My doctor thought I would never be able to improve the range of motion in my left arm. Her recommendation was to surgically remove the implant.

During the few weeks following my initial

appointment, the pain and burning in my chest worsened. I could not sleep at night because I could feel the implant moving around, shifting and painfully poking me. Then I had the ultimate breast implant nightmare. I stepped out of the shower on June 1, 2000. I knew it had happened to me. My breast was gone.

One week later I was in an outpatient operation room, terrified. After five hours of surgery to remove the implants, I woke up to find out that Dr. Feng had removed one deflated saline breast implant and the other device in my body which had been a solid silicone block.

My insurance did approve the procedure, but I still had to pay 20 percent up front, which amounted to $2000, and I was required to stay in a hotel room for five days so that the doctor could monitor my progress and remove my drains. The total cost of my trip was $3000. I had to take out a loan in order to pay for what the insurance had not covered.

Had I known the additional physical and emotional consequences of receiving breast implants, I would have made a different decision. When I opted for reconstructive surgery I did my

homework. I read what little research was out there. Only now do I know that the research that was available was conducted by the manufacturers.

As a young woman and a consumer, I ask you to require and enforce the most stringent guidelines on the integrity of applications and of the manufacturers submitting applications for device marketing approval and clinical trials. I ask that long-term follow-up on the adverse events be demanded of all manufacturers, with close oversight by FDA. Only through this process will consumers ever have access to accurate surveillance data on complications and failure rates of breast implant devices.

Until there is incentive for manufacturers to make better, safer and more effective devices, women will continue to risk their health, their future, and possibly their lives by choosing these FDA approved medical devices. Thank you.

DR. WHALEN: Thank you. I realize that was a reading of a statement but does anybody have any questions?

[No response]

Thank you.

MS. MCDONOUGH: Thank you very much.